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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
| 09/380,534 | 09/01/99 | KUNDIG | C9015-2007 |

QM12/0525

KNOBBE MARTENS OLSON & BEAR LLP
620 NEWPORT CENTER DRIVE
SIXTEENTH FLOOR
NEWPORT BEACH CA 92660

EXAMINER

HAYES, M

ART UNIT PAPER NUMBER

3763

DATE MAILED: 05/25/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Applicati n No.

09/380,534

Applicant(s)

KUNDIG, THOMAS M.

Examiner

Michael J Hayes

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-65 is/are pending in the application.
- 4a) Of the above claim(s) 22-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 38-65 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.9.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-21, 39-41, 43-53, 55-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over PUCETTI et al. or GROHMANN et al. in view of ELLIOTT et al. (U. S. Patent No. 5,478,556), NABEL al. (U. S. Patent No. 5,348,470), AMKRAUT et al. (U. S. Patent No. 4,439,199) and/or MERTELSMANN et al. (U. S. Patent No. 4,908,433). Puccetti discloses intrasplenic immunization by depositing a tumor or influenza virus antigen in the splenic capsule (pgs 1447-1449). Grohmann discloses a method of immunizing including depositing an antigen into a lymph node or spleen (pg. 9), eliciting CTL responses to tumor antigens by intrasplenic immunization (pg. 10), and use of multiple antigens. Puccetti and Grohmann do not teach a method of administering the antigen via catheter to a lymph node or spleen. Mertelsmann teaches using an implanted osmotic pump to deliver cytokine, IL-2. Nabel teaches using a catheter to deliver drugs to the lymph system (i.e. thymus) to modulate the immune system (col. 4, lines 9-22). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Mertelsmann or Nabel in the invention of Puccetti or Grohmann in order to administer drug treatment to a specific site within the body. Amkraut teaches a method of sustained regular delivery of immunomodulators over a time to treat a disease. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the

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teachings of Amkraut in the invention of Puccetti or Grohmann in order to enhance the immune response during the course of a disease. Puccetti or Grohmann do not disclose administering an antigen and cytokine to induce a CTL response. Elliott teaches inducing a CTL response using tumor-associated antigens (CA 19-9) and cytokines (col. 2, lines 31-57; col. 3, lines 28-37) to enhance the immune response. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Elliott in the methods of Grohmann, Puccetti, Mertelsmann, Nabel, or Amkraut to improve treatment results.

Re claims 43-60 reciting the specific forms of the antigen it would have been obvious to one of ordinary skill in the art at the time of the invention to use any of the well-known forms of CTL-inducing antigens.

Conclusion

3. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. LEONARD (U. S. Patent No. 5,409,710) shows delivery to a lymph node. ALVING et al. (U. S. Patent No. 5,910,306) discloses a delivery system for various antigens.

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel, can be contacted at (703) 308-5115. The fax number for submitting papers is (703) 305-3590.



Michael J. Hayes
18 May, 2001